

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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D.P.,		:
		:
	Plaintiff,	:
		:
v.		:
		:
JUUL LABS, INC.,		:
		:
	Defendant.	:
		:
-----		X

No. 7:18-CV-05758 (CS)

Oral Argument Requested

**DEFENDANT’S REPLY MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO DISMISS**

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PRELIMINARY STATEMENT

Plaintiff D.P.’s Opposition seeks to inject new theories of liability that are not pleaded in the Amended Complaint (“FAC”) or are unsupported by New York law, and to distract the Court from the judicially noticeable warning label on JLI’s product packaging. Nothing in the Opposition saves the FAC, which should be dismissed for failure to state any claim for relief.

ARGUMENT

A. The FAC Fails to State a Claim for Defective Design

1. The FAC does not allege any actual defect.

Plaintiff’s Opposition maintains that JUUL products are defective for three reasons: (1) they allegedly contain too much nicotine; (2) they are flavored and do not irritate the user’s throat as much as combustible cigarettes do; and (3) they were allegedly advertised through “youth oriented marketing.” *See* Dkt. No. 60 (“Opposition” or “Opp.”) at 10, 11–12. None of these allegations plausibly supports a defective design claim.

Nicotine Level: Plaintiff’s Opposition attempts to reframe his allegations, but what matters are the allegations in the FAC. *See, e.g., Palatkevich v. Choupak*, 2014 WL 1509236, at *9 (S.D.N.Y. Jan. 24, 2014) (“Plaintiffs cannot add allegations through their opposition brief.”). The FAC asserts that JUUL products are defective because they contain an addictive amount of nicotine and JLI could have designed a product “that would contain far less nicotine or would contain nicotine in a formulation which was less likely to addict its users.” FAC ¶¶ 77–79. These conclusory allegations do not support a claim of design defect. The asserted defect relates to, and the proposed alternative vitiates, the intrinsic function of JUUL products—to deliver nicotine to satisfy smokers. But “[a]s a matter of [New York] law, a product’s defect is related to its condition, not its intrinsic function.” *Tuosto v. Philip Morris USA Inc.*, 2007 WL 2398507,

at *12 (S.D.N.Y. Aug. 21, 2007) (internal quotation marks omitted); *see also Adamo v. Brown & Williamson Tobacco Corp.*, 11 N.Y.3d 545, 549 (2008).¹

Faced with these arguments, Plaintiff now asserts that JUUL products are defective because they contain more nicotine than cigarettes. To the extent the FAC even makes this allegation, it is vague, conclusory, and not cognizable. Plaintiff cites to just one paragraph of the FAC to support this argument. *See* Opp. at 5, 12. Indeed, the most the FAC alleges is that “JUUL’s patented formulation . . . causes a peak nicotine-blood concentration (‘Cmax’) of approximately 15 mg/mL, compared to a Cmax of 11 mg/mL for a Pall Mall cigarette,” and that “[a] comparison of studies . . . indicated that JUUL delivers 36 percent more nicotine than Marlboros.” FAC ¶¶ 32–33. This allegation is utterly devoid of context—with no allegation of what is being compared to a cigarette, or why—and falls far short of pleading that the nicotine content of JUUL products is excessive, much less that it is a design defect. And even if the FAC had included non-conclusory allegations through some meaningful consumption comparison that JUUL products did deliver more nicotine than cigarettes (which it has not), the FAC does not allege *why* a higher level of nicotine—whose presence is disclosed on the JUUL product’s label and whose addictive quantities are well known²—is a design defect.

Indeed, Plaintiff ultimately falls back on the FAC’s core contention—that JUUL products are defective merely because they contain nicotine—by suggesting as a potential alternative “a product with less nicotine *or even no nicotine*.” Opp. at 17 (emphasis added). But Plaintiff

¹ In an effort to avoid this conclusion, Plaintiff quotes an article purportedly suggesting that JUUL products were intended for nonsmokers, because they are for “consumers who aren’t perfectly aligned with traditional tobacco products.” *See* Opp. at 2, 4, 12, 16. But that article *does not even discuss JUUL products*: it references a product called Ploom that Plaintiff does not allege using. *See* FAC ¶ 13 (citing Josh Mings, *Ploom modelTwo Slays Smoking with Slick Design and Heated Tobacco Pods*, SolidSmack, Apr. 23, 2014).

² These labels’ existence alone dooms the FAC. *See* Dkt. No. 59 (“Def. Br.”) at 12–13.

cannot articulate a legally cognizable basis for distinguishing the cases that foreclose such a claim. *See generally* Def. Br. at 8–11.³ Plaintiff suggests that other courts have sustained similar claims by citing *Grisham v. Philip Morris, Inc.*, 670 F. Supp. 2d 1014 (C.D. Cal. 2009), but that case involved a claim under *California* law that “light” cigarettes delivered *too little* nicotine, which caused smokers to “compensate” by smoking more and inhaling more toxins, *id.* at 1041.⁴ Plaintiff does not assert (nor could he) that JUUL products, even if they do contain more nicotine than a cigarette, are more harmful than the deadly cigarettes that they are designed to replace.

The Products’ Taste and pH level: That JUUL products taste good and do not hurt consumers’ throats as much as cigarettes are *not* defects. *Contra* Opp. at 11–12, 15–16. Under New York law, design defect claims normally concern such issues as “phones unexpectedly catching fire, car ignition switch flaws, [or] drugs substantially increasing the risk of heart attack and death,” *Fasolas v. Bobcat of N.Y., Inc.*, 2019 WL 2030249, at *9 (N.Y. May 9, 2019), not features that make a product *desirable*. Flavoring in ENDS is undoubtedly an important policy issue, and is being considered by the FDA, *see* Def. Br. at 5, but such flavoring does not make a product “defective.” For example, high-quality, flavored vodka is not defective because it could have been made to taste worse to deter consumption. Plaintiff cites *no legal support* for the FAC’s attempt to cast an improvement to the taste of an adult-only product as a “defect.” It is not plausible to suggest that only minors—and not adults—find utility in good-tasting products.

³ Plaintiff *attempts* to do so by arguing that “it could certainly be inferred” that the FAC alleges that JUUL products contain more nicotine than typical cigarettes, Opp. at 13, but that line of reasoning fails for the reasons emphasized above: one cannot plausibly conclude from unexplained comparisons between JUUL products and specific cigarette brands that JUUL products contain so much more nicotine than all cigarettes so as to be actionably defective. *See, e.g., Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

⁴ *Rogers v. R.J. Reynolds Tobacco Co.*, 557 N.E.2d 1045 (Ind. Ct. App. 1990), the other out-of-state case to which Plaintiff cites, contains no analysis of the issue and certainly does not provide a basis to apply Indiana law to a New York-based dispute, *see id.* at 1055.

Plaintiff's suggestion that JUUL's products are defective because they do not have a harsh "throat hit" like cigarettes is equally implausible. A product is not defective because it is smooth. Plaintiffs cannot maintain a product defect claim on the theory that JLI should have irritated JUUL users' throats and airways. Defective products must be "unsafe products," *see Fasolas*, 2019 WL 2030249, at *9, and Plaintiff's flavor and pH level theories simply do not support a claim that JUUL products are unsafe.

Marketing: Plaintiff's Opposition argues for the first time that JLI's marketing is a product defect. The FAC did not raise this theory as a basis for the product defect claim, and therefore it cannot support that claim. *See* FAC ¶¶ 72–86. In any event, this theory fails because *marketing* is not a defect in *design*; an advertisement does not impact a product's condition. *See, e.g., Tuosto*, 2007 WL 2398507, at *12 (noting design defect claims must concern a product's "condition"); *Forni v. Ferguson*, 648 N.Y.S.2d 73, 74 (1st Dep't 1996) (same).

2. Plaintiff does not allege a feasible alternative design.

JLI's motion explained that Plaintiff's proposed alternative design—a product with little or no nicotine—is not a feasible alternative design for a product designed to deliver nicotine to smokers. *See* Def. Br. at 15–16. Unable to muster a legal response, Plaintiff asks this Court to ignore the basic purpose of the product that is the subject of the design defect claim. *See* Opp. at 16. But the law provides otherwise. *See, e.g., Haywood v. Republic Tobacco, Co.*, 2007 WL 1063004, at *3 (W.D.N.Y. Apr. 6, 2007) (noting on grant of motion to dismiss that the "very purpose" of "tobacco . . . is for smoking and the potential health consequences of inhaling the smoke produced when the loose tobacco is put to its intended use cannot be designed away"). As the Court of Appeals stressed in *Adamo v. Brown & Williamson Tobacco Corp.*, 11 N.Y.3d 545 (2008), "satisfying the consumer is the only function [of a cigarette]," and a proposed alternative is not feasible if it cannot give the same amount of "pleasure to a smoker," *id.* at 550–

51. Plaintiff ignores that reality. He suggests that JLI should have designed a product with “less nicotine or even no nicotine,” Opp. at 17, but delivering a satisfying amount of nicotine without the deadly products of combustion is the whole point of the JUUL product, and the reason many adult smokers switch away from combustible cigarettes. Plaintiff’s alterations would prevent, or at least interfere with, the product achieving its purpose of providing a meaningful alternative to combustible cigarettes. These are “not feasible alternative designs in any meaningful sense,” and are akin to the “‘non-addictive’ cigarette designs [that] were indisputably rejected by consumers” in *Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 648 (S.D.N.Y. 2007).

Plaintiff’s other suggestions—that the product should never be offered in flavors other than tobacco and that it should irritate the user’s throat, *see* FAC ¶¶ 80–81—are also not feasible alternatives. Adopting alterations that would make the product taste worse and potentially be more irritating to the user’s throat would simply make the product *less* satisfying to adult smokers, thereby failing the “risk-satisfaction” analysis set forth in *Adamo*, *see* Def. Br. at 15–16. Moreover, these alterations would not change the nicotine concentration, which is at the heart of Plaintiff’s claim.

3. Plaintiff did not use JUUL products in their intended manner.

JUUL products are prominently labeled “NOT FOR SALE TO MINORS. Keep away from children” Dkt. No. 61, Ex. 8. Thus, Plaintiff, a minor, did not use the products as intended, which is required for a product defect claim under New York law. *See Hartnett v. Chanel, Inc.*, 948 N.Y.S.2d 282, 285 (1st Dep’t 2012). Plaintiff would like this Court to ignore the product label, *see* Opp. at 17, but that label is a proper subject of judicial notice—and its content defeats the claim. “While a court must generally accept a plaintiff’s factual allegations as true in evaluating a motion to dismiss, it need not accept as true allegations in a complaint that contradict or are inconsistent with judicially-noticed facts.” *Becker v. Cephalon, Inc.*, 2015 WL

5472311, at *5 (S.D.N.Y. Sept. 15, 2015) (internal quotation marks omitted); *see also* Def. Br. at 4 n.2 (compiling cases endorsing the consideration of warning labels). Further, this Court can take judicial notice that New York prohibits the sale of tobacco products to minors. *See* N.Y. Pub. Health Law § 1399–cc(2). The foreseeability cases Plaintiff cites are all distinguishable, as they involve lighters, the sale of which is not restricted to adults. *See* Opp. at 18.

B. The Court Should Dismiss Plaintiff’s Failure to Warn Claim

Plaintiff’s failure to warn claim is foreclosed by the existence of a warning on the product, *see* Def. Br. at 21, but Plaintiff asserts that the Court should ignore this fact, *see, e.g.*, Opp. at 21. A plaintiff cannot will a warning label out of existence merely because it undermines his cause of action. As noted above, the product label is a judicially noticeable fact. That Plaintiff does not even attempt to argue that the judicially noticeable FDA-approved warning label was inadequate underscores that the label’s existence is fatal to the claim.

Plaintiff also does not rebut JLI’s arguments that this claim fails for lack of causation, improperly seeks to impose liability for an obvious risk, and is foreclosed by federal preemption.

Lack of Causation: The FAC admits that “the packaging [of JUUL products] was never seen by D.P.” FAC ¶ 90. This concession defeats the claim, because no different or additional label on the packaging would have prevented the alleged harm. Plaintiff resorts to arguing that JLI should have put a warning on the device itself and on the tiny JUULpods that plug into the device. *See* Opp. at 19. Apart from this argument being foreclosed by federal preemption, *see infra*, Plaintiff also does not identify *any* law or precedent holding that manufacturers who place warnings on their products’ packaging are also under an obligation to place additional warnings on each individual product unit inside of that packaging. This lack of support is unsurprising. *Cf.* Restatement (Second) of Torts § 402A cmt. j (1965) (“Where warning is given, the seller may reasonably assume that it will be read and heeded.”). As the FDA has noted, “package

warnings are . . . delivered to tobacco users at the two most important times—when users are considering using or purchasing the tobacco product.” 81 Fed. Reg. 28974, 29064 (May 10, 2016). Nothing else is required.

Plaintiff also attempts to manufacture causation by arguing that his use was the result of “endemic” use of JUUL products. *See* Opp. at 21. This theory is, however, entirely unsupported by the FAC. “New York product liability cases . . . require that the plaintiffs plead . . . that they would not have been injured by the non-defective product.” *Caronia v. Philip Morris USA, Inc.*, 2011 WL 338425, at *11 (E.D.N.Y. Jan. 13, 2011). The FAC does not mention how, when, where, or, most critically, *why* these people began to use the product, much less allege that these unidentified people would have refrained from using JUUL products had those products contained a different warning. *See* FAC ¶ 63. Plaintiff cites to no New York law that would allow him to ignore product warnings but bring a failure to warn claim because other people used the product.⁵ Accordingly, this new theory lacks plausibility and must be rejected.

Open and Obvious Risk: Plaintiff also has no response to JLI’s argument that it affirmatively disclosed that JUUL products contain nicotine, and it had no further duty under New York law to warn of the open and obvious risk of nicotine addiction. *See* Def. Br. at 22–23. Plaintiff cites a study for the proposition that some minors may not have known that JUUL products always contain nicotine. *See* Opp. at 23 (citing FAC ¶ 34). But this is not relevant to *what Plaintiff knew*. The FAC concedes that Plaintiff had previously tried cigarettes, *see* FAC ¶ 64, and it fails to allege that he did not know that JUUL products contained nicotine, or that

⁵ Plaintiff asserts that “causation is established in these circumstances,” but cites four different cases involving *misrepresentations* or *deception*. *See* Opp. at 21–22. Moreover, three of the four cases did not apply New York law, and the fourth concerned a false advertising claim which is subject to a lower standard of causation, *see In re Opioid Litig.*, 2018 WL 3115102, at *20–21 (N.Y. Sup. Ct. June 18, 2018).

nicotine is addictive. But even those allegations would not save the FAC, because the open and obvious rule uses an *objective* standard. *See Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 540 n.31 (S.D.N.Y. 2003). Further, contrary to Plaintiff's assertion, *see* Opp. at 15, *this District* has ruled that minors should be held to the same objective standard as adults for the purposes of the rule, *see Pelman*, 237 F. Supp. 2d at 540 n.31 (“[S]everal cases involving underage alcohol consumption [] hold that minors should be held accountable for the same body of common knowledge of risks posed by alcohol consumption.”); *see generally Peters v. City of N.Y.*, 269 A.D.2d 581, 582 (2d Dep’t 2000) (applying exception to minor); *Josue v. Isuzu Motors Am., Inc.*, 958 P.2d 535, 540 n.5 (Haw. 1998) (applying exception notwithstanding survey showing that teenagers were unaware of dangers of riding in truck bed). Given the widespread recognition of nicotine’s addictive properties, JLI had no duty to disclose this obvious risk beyond identifying that the product contained nicotine. *See, e.g., Small v. Lorillard Tobacco Co., Inc.*, 679 N.Y.S.2d 593, 600 (1st Dep’t 1998) (finding such a claim of ignorance implausible on a motion to dismiss *decided in 1998*); *see also* Def. Br. at 12–13.

Preemption: Plaintiff’s failure to warn claim is preempted because it is premised on the assertion that JLI should have used different warnings to inform Plaintiff of alleged risks. 21 U.S.C. § 387p(a)(2)(A) grants the FDA authority to regulate warning labels, which preempts failure to warn claims. Plaintiff also asserts that JLI should have added warnings to the device itself or to the tiny JUULpods, *see* Opp. at 19, but this argument is preempted because, as noted, the FDA has exclusive control over labeling requirements, and the definition of “labeling” extends not only to the packaging of an article, but also to *the article itself*, *see* 21 U.S.C. § 321(m). Plaintiff points to the savings provision of the TCA to argue that his failure to warn claim is not preempted. *See* Opp. at 19. While true that product liability claims *generally* are

not preempted, such claims cannot be premised on an inadequacy of federal labeling because holding otherwise would allow states to impermissibly require additional or different labeling than that mandated by the FDA. *See Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Akee v. Dow Chemical Co.*, 272 F. Supp. 2d 1112, 1133 (D. Haw. 2003). Indeed, in *Colgate v. JUUL Labs, Inc.*, 345 F. Supp. 3d 1178 (N.D. Cal. 2018), the court found, on facts nearly identical to those presented here, that “claims based on the allegation that the product labeling fails to warn consumers that JUUL’s nicotine formulation is more addictive than other methods of nicotine ingestion are expressly preempted,” *id.* at 1190. Plaintiff’s contention that *Colgate*’s preemption discussion “applied only to the plaintiffs’ false advertising claim,” Opp. at 20, is simply false, *see Colgate*, 345 F. Supp. 3d at 1188–90.

C. The Court Should Dismiss Plaintiff’s Negligence Claim

Plaintiff styles the FAC’s negligence claim as an amalgam of a negligent marketing claim and a negligent design claim, *see* Opp. at 25, yet he fails to cite any case permitting such a mixed claim.⁶ Instead, Plaintiff invents a duty out of whole cloth, claiming that “[a]s a seller of a nicotine product ostensibly intended for adults, JUUL owed a duty to minors to design and market the product in a way such that it would not appeal to children.” Opp. at 23.⁷ This makes no sense: such a duty would allow the preferences of those individuals for whom a product is *not* designed to dictate the design and marketing of that product, and would impose liability whenever such manufacturers made their products more universally appealing. “In fixing the bounds of [] duty, not only logic and science, but policy play an important role.” *Strauss v. Belle*

⁶ To the extent this Court treats the negligence claim as two distinct claims—a negligent design claim and a negligent marketing claim—those claims fail for the reasons alleged in JLI’s opening brief. *See* Def. Br. at 23–25.

⁷ The only case to which Plaintiff cites, *Solomon v. City of N.Y.*, 66 N.Y.2d 1026 (1985), is inapposite. There, the court found that there was no duty for a city to police and prevent bike riding in a park area where bike riding had been prohibited. *Id.* at 1027.

Realty Co., 65 N.Y.2d 399, 400 (1985) (internal quotation marks omitted). Plaintiff’s attempt to use duty to yoke manufacturers to those for whom their products are not intended is illogical and contrary to public policy, and would result in crushing exposure to such manufacturers. It accordingly must fail. *See, e.g., Pulka v. Edelman*, 40 N.Y.2d 781, 783–86 (1976) (no duty for garage to control the conduct of its patrons for the protection of off-premises pedestrians).

The freestanding negligence claim also fails due to a lack of causation. Courts have uniformly rejected similar theories brought against manufacturers of adult-only products based on a lack of causation and duty, and because whether to punish advertisements that may appeal to both adults and minors is a legislative policy issue and raises grave constitutional concerns.⁸ In any event, because the FAC does not allege that JLI’s marketing played any role in Plaintiff’s decision to use JUUL products, the claim fails. *See* Def. Br. at 25.⁹

CONCLUSION

JUUL Labs, Inc. respectfully requests that this Court grant its motion to dismiss. Because Plaintiff was already permitted to amend the Complaint but did not cure the deficiencies, the FAC should be dismissed with prejudice in its entirety.

⁸ *See, e.g., Bertovich v. Advanced Brands & Importing, Co.*, 2006 WL 2382273, at *11 (N.D. W. Va. Aug. 17, 2006); *Alston v. Advanced Brands & Importing Co.*, 2006 WL 1374514, at *9 (E.D. Mich. May 19, 2006), *vacated on other grounds by Alston v. Advanced Brands & Importing Co.*, 494 F.3d 562 (6th Cir. 2007); *Eisenberg v. Anheuser-Busch, Inc.*, 2006 WL 290308, at *15 (N.D. Oh. Feb. 2, 2006) (same); *In re Tobacco Cases II*, 20 Cal. Rptr. 3d 693, 709 (Cal. Ct. App. 2004).

⁹ *In re Opioid Litig.*, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018)—the only case Plaintiff cites to support the marketing element of the negligent marketing claim—is distinguishable because, among other things, it featured allegations of “*deceptive marketing campaigns*,” *id.* at *34 (emphasis added). Here, the FAC merely alleges that JLI ran one advertising campaign marketing its product as “a cool, hip, stylish accessory” in “youth-centric media,” FAC ¶ 71; it *does not* cite to any evidence of a causal relationship between JLI’s Vaporized campaign, *see* FAC ¶¶ 39–52, and the “pervasive” use of JUUL products at Plaintiff’s high school, *see id.* ¶ 63. Plaintiff cites no authority for imposing liability in such situations.

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